MAY 06 2002 K011690

# 510(k) Summary of Safety and Effectiveness

## 1. General Information

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|---|---|
| **Applicant's Name and Address:** | Proxima Therapeutics, Inc.<br>2555 Marconi Drive, Suite 220<br>Alpharetta, GA 30005-2066 |
| **Contact Person:** | Deborah J. Moore<br>VP, Regulatory and Clinical Affairs<br>Telephone: 770-753-4848<br>Fax: 770-753-4937 |
| **Proprietary Name:** | MammoSite™ Radiation Therapy System (RTS) |
| **Common Name:** | Remote-controlled radionuclide applicator system |

## 2. Device Description

The MammoSite™ RTS is a radiation therapy system that includes the MammoSite RTS Catheter Tray and the MammoSite HDR Afterloader Accessories Tray. The MammoSite RTS Catheter Tray includes the MammoSite catheter and accessories to assist with the implantation of the catheter. The MammoSite catheter is a shaft with an inflatable balloon that positions the radiation source within the resected cavity for radiation delivery. The MammoSite is a variable 4 cm - 5 cm spherically inflated balloon. The MammoSite Afterloader Accessories Tray contains the items needed to connect the afterloader to the MammoSite RTS.

## 3. Intended Use of Device

The MammoSite Radiation Therapy System is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

## 4. Predicate Devices

The MammoSite RTS is substantially equivalent to Proxima Therapeutics, Inc.'s GliaSite Radiation Therapy System (K003206) and Nucletron Corporation radionuclide applicator systems (K853912, K864210, K953946, K983337, K983341) in terms of its technical specifications, intended use and method of application.

## 5. Comparison of Technological Characteristics

The intended use, clinical performance, and technological characteristics of the MammoSite RTS are similar to those of commercially available brachytherapy applicators used with sealed radiation sources. Comparison of the MammoSite RTS to these devices included implant duration, target sites, component materials and dimensions, radionuclide source, and clinical usage.

The MammoSite has the same intended use, similar technological characteristics, and similar materials/dimensions of the predicates. Although the indication for use is not identical to the predicate devices, the intended use is the same and the difference does not introduce any new questions about safety or effectiveness. These devices provide a means of delivering a radiation therapy in a tumor or tumor cavity. The MammoSite and brachytherapy applicators position the radioactive source for radiation therapy. The MammoSite and brachytherapy applicators utilize $^{192}$Ir seed or ribbon as the radiation source with similar dosimetric properties.

Any differences that exist between the MammoSite RTS and the predicate devices were discussed and have shown that these differences do not affect safety or effectiveness. It was demonstrated that the MammoSite RTS is substantially equivalent to the predicate devices.

## 6. Preclinical Tests

Extensive preclinical testing was conducted to evaluate and characterize the performance of the MammoSite RTS. Preclinical studies conducted included in vitro laboratory studies to demonstrate that the MammoSite catheter, its accessories and packaging performed as intended under simulated use and challenge conditions. Biocompatibility testing was performed to demonstrate that the materials meet the requirements. The dosimetry of the MammoSite was characterized. Based on these findings, it was concluded that the MammoSite RTS could deliver an equivalent radiation dose to current brachytherapy applicators. Finally, animal studies were conducted to illustrate the performance of the device that included successfully delivering a clinical dose of brachytherapy.

## 7. Clinical Studies

A multi-center phase II clinical study was conducted to evaluate the safety and effectiveness of the MammoSite RTS. The study included breast cancer patients who were undergoing tumor resection. Assessment methods used to evaluate safety and effectiveness included radiological and clinical measures. Brachytherapy was successfully delivered to all patients. A complete clinical summary including data analysis and individual patient data was provided to FDA. The clinical study demonstrated that the MammoSite RTS is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2002

Ms. Deborah Moore
Vice-President, Regulatory & Clinical Affairs
PROXIMA THERAPEUTICS, Inc.
2555 Marconi Drive, Suite 220
ALPHARETTA GA 30005-2066

Re: K011690
Trade/Device Name: MammoSite™ Radiation Therapy System (RTS)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: February 7, 2002
Received: February 8, 2002

Dear Ms. Moore:

This letter corrects our substantially equivalent letter of May 6, regarding the contents of the Statement of the Indications for Use enclosure.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

**The safety and effectiveness of the MammoSite RTS as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.**

The Warning must be presented within a black box, and the font should be bold and the same size as any surrounding text. The Warning should be the first item in your list of warnings.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**510(k) Number (if known):** K011690

**Device Name:** **MammoSite Radiation Therapy System (RTS)**

FDA's Statement of the Indications for Use for device:

The MammoSite Radiation Therapy System is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011690

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)